

Remarks

An English translation of the Application is enclosed herewith. The fee for late filing of an English translation was paid when the Application was filed.

The Applicants have amended the Title and the Specification to provide related application information and to place the Application into proper condition for examination. The Claims have been cancelled and a new set of Claims 20 – 38 have been added. An Abstract has been added. Examination on the merits is respectfully requested.

A copy of an executed Combined Declaration, Power of Attorney and Petition is also enclosed. The fee for late filing of the Declaration was paid when the Application was filed.

Passage to the appropriate art unit for examination on the merits is respectfully requested.

Respectfully submitted,



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SUBSTITUTE SPECIFICATION (Marked-Up)

DYNAMIC ~~CONNECTING~~LINKING ELEMENT FOR A SPINAL ~~FIXING~~ATTACHMENT SYSTEM, AND A ~~FIXING~~SPINAL ATTACHMENT SYSTEM COMPRISING SUCH A ~~CONNECTING~~INCLUDING SAID LINKING ELEMENT

Related Application

[0001] This is a §371 of International Application No. PCT/FR2005/000496, with an international filing date of March 2, 2005 (WO 2005/087121 A1, published September 22, 2005), which is based on French Patent Application No. 04/02150, filed March 2, 2004.

Technical Field

[0002] The ~~present~~ invention relates to the field of spinal fixing systems for connecting vertebrae together, more particularly to the field of connecting elements intended to maintain ~~the~~ spacing between at least two anchoring elements implanted respectively in a vertebra.

Background

[0003] There exist currently two types of spinal connections: on the one hand osteosynthesis connections and on the other hand dynamic connections.

[0004] Spinal osteosynthesis connections are well known connections. ~~There~~They are ~~in fact~~ frequently used ~~for consolidating~~to consolidate several consecutive vertebrae. Their purpose is to immobilize the vertebrae connected in a particular configuration and ~~to stabilise~~stabilize them during the bone fusion ~~in order to~~ allow fixed ~~stabilisation~~stabilization in the immobilized situation. Such connections consist of rigid rods.

[0005] On the other hand, dynamic connections are used to reduce stresses on the articular facets and [[on]]intervertebral discs by allowing certain movements, ~~whilst~~ while, if necessary, realigning the vertebrae with respect to one another.

~~[0006] The prior art already knows such connecting elements.~~

[0007] ~~In particular, EP 0 669 109 discloses a device for stabilising~~ stabilizing adjoining dorsal vertebrae ~~is proposed in the European patent application EP0669109. The said~~ That device comprises a connecting element consisting of a band produced from elastic synthetic material and having a round transverse section. ~~This~~ The band is intended to be fixed between at least two pedicular screws consisting respectively of a head provided with a transverse piercing. The ~~said~~ band is fixed to the ~~said~~ pedicular screws by inserting, through the transverse piercing, the ~~said~~ band, which is then fixed to each of the ~~said~~ pedicular screws by means of a clamping screw disposed along the axis of the corresponding screw, that is to say transversely to the piercing. The ~~said~~ device also comprises a support element mounted around the ~~said~~ band ~~in order to~~ form a body resisting pressure.

[0008] Such a connecting element does, however, have the drawback of not effecting any torsion return ~~in order to~~ oppose pivoting movements of the vertebrae around the discs.

[0009] Another important drawback of ~~this~~ that connecting element is that it cannot be curved so as to adapt to the natural lordosis of the lumbar vertebral column.

[0010] In addition, another drawback is that the connecting element occupies a large volume (around 12.5 mm). In some circumstances, it may prove to be difficult to prevent the connecting element in question from coming into contact with the bones, such a contact causing a great deal of pain.

[0011] Moreover, such a device has a particularly important drawback relating to the need to choose the length of the support element before fitting the ~~said~~-band. It may happen however that the effective distance between the screws after tensioning the band is not exactly that desired. However, the device as configured allows no freedom of relaxation and/or compression between the screws after the fitting of the band and support element. The surgeon therefore has no other choice than to remove the assembly consisting of support element and band in order to introduce a new support element having a different length.

[0012] ~~There is also proposed, in international patent application WO 02/07621~~[[,]] discloses a connecting piece intended to maintain [[a]]the spacing between at least two anchoring elements screwed into vertebrae, the ~~said~~-connecting piece comprising: i) a flexible part divided into two continuous branches spaced apart from each other, the ~~said~~-branches being substantially symmetrical with respect to the longitudinal axis of the ~~said~~-piece, the ends of the ~~said~~-branches being connected together in pairs and defining a first mean plane, and ii) two rigid parts forming rods, having a first fixing portion and a second portion, each ~~said~~-second portion of the ~~said~~-two rigid parts respectively extending in opposite directions from the ~~said~~-ends of the ~~said~~-branches connected together in pairs, the cross-section of each of the ~~said~~-branches being less than the cross-section of the ~~said~~-rigid parts so that the ~~said~~-connecting piece, whose fixing portions are fixed respectively to each of the two anchoring elements, is able to bend elastically perpendicular to the ~~said~~-mean plane during ~~the~~-relative movement of the vertebrae, by means of which the vertebrae, kept spaced apart from one another, are able to move with respect to one another.

[0013] ~~This~~That connecting piece does, however, have the drawback of being able to bend only in one clearly determined direction, namely perpendicular to the mean plane formed by the two branches. The result is a mounting of the whole of the ~~stabilisation~~stabilization system com-

prising such connecting pieces requiring a certain amount of precision and therefore possibly proving tedious. Another drawback of such a connecting piece ~~also proves to be~~ is its volume.

Summary

[0014] This disclosure relates to a connecting element for a spinal fixing system that connects at least two implantable connection assemblies including a rod including a flexible part extended at one end at least by a rigid part, the flexible part including a cable at least partly surrounded by a polymer envelope, the cable including at least one elastic strand coaxial with the envelope.

Brief Description of the Drawings

[0015] The disclosure will be understood better with the help of the description given below, purely by way of explanation of a selected, representative example, with reference to the accompanying figures:

Fig. 1 illustrates a lateral view in perspective of a dynamic connecting element;

Fig. 2 illustrates another of the connecting elements of Fig. 1;

Fig. 3 illustrates a view in section of the connecting element of Fig. 2;

Fig. 4 illustrates a partial view in perspective of a spinal fixing system comprising rigid connecting elements and dynamic connecting elements; and

Fig. 5 illustrates a view in section of a semi-dynamic connecting element.

Detailed Description

[0016] ~~A first object of the invention is to remedy the drawbacks of the dynamic connecting elements described above by proposing~~We provide a connecting element having an amplitude of flexion equivalent with regard to the~~[[se]]~~ dynamic connecting elements, but whose holding in rotation is ensured.

[0017] The ~~said~~ connecting element ~~that is the object of the invention~~ also has the advantage of being able to be curved so as to adapt to the natural lordosis of the lumbar vertebral column.

[0018] The ~~said~~ connecting element ~~that is the object of the invention~~ also has the advantage of being not very invasive, ~~whilst~~while providing the functionalities required for a dynamic connecting element (flexibility, resistance to wear, etc).

[0019] The ~~said~~ connecting element also has the advantage of allowing rapid mounting on the anchoring elements fixed to the vertebrae.

[0020] ~~Finally, the said~~The connecting element has the advantage of being able to undergo relaxation and/or compression after its fitting on the anchoring elements.

[0021] To do this, ~~the present invention concerns~~we provide a connecting element for a spinal fixing system intended to connect at least two implantable connection assemblies, the ~~said~~ connecting element ~~being remarkable in that it consists of~~including a cable and a polymer envelope surrounding the ~~said~~ cable, the ~~said~~ cable ~~consisting of~~including at least one elastic strand coaxial with the ~~said~~ envelope ~~so as to~~ form the core of the connecting element.

[0022] ~~In order not to burden the rest of the description, the said~~The strand forming the core of the ~~said~~ connecting element is defined as the “central strand” for ease of understanding.

[0023] Preferably, the ~~said~~ connecting element comprises at least one layer of at least six strands distributed around the ~~said~~ central strand.

[0024] According to ~~an advantageous one configuration of the invention~~, the ~~said~~ connecting element comprises two layers of successive strands disposed around the ~~said~~ central strand, the first layer of strands surrounding the ~~said~~ central strand consisting of 6 strands, the second layer of strand surrounding the ~~said~~ first layer consisting of 12 strands.

[0025] Advantageously, the strands constituting the layer or layers ~~consist of~~ include strands twisted around the ~~said~~ central strand.

[0026] Advantageously, the strands of the layer or layers ~~consist of~~ may be a material different from that of the ~~said~~ central strand.

[0027] Advantageously, the central strand has a diameter different from that of the strands of the ~~said~~ layer or layers. According to the type of configuration required, it may be less than or greater than that of the strands of the ~~said~~ layers.

[0028] Advantageously, the strands constituting the layer or layers ~~consist of~~ may be titanium or stainless steel.

[0029] Advantageously, the central strand is tubular.

[0030] Advantageously, the central strand ~~consists~~ may be made of a nickel-titanium alloy, titanium, stainless steel or polymer, such as for example PEEK or polyurethane.

[0031] Advantageously, the ~~said~~ envelope is made from polyurethane or PEEK or ~~consists of~~ a biocompatible fabric.

[0032] ~~A second object of the invention is to propose~~ We also provide a connecting element combining the functionalities of a dynamic connecting element with those of an osteosynthesis connecting element. More particularly, ~~the object of the said connecting element is to propose~~ provides, conjointly with a dynamic connection of at least two vertebrae, the rigid connection of other vertebrae.

[0033] This is because, in the case of the fitting of a multilevel vertebrae fixing and ~~stabilisation~~stabilization system (instrumentation of several vertebrae) it may prove necessary to connect certain vertebrae together by means of a dynamic connection ~~in order~~ to allow certain movements, and on the other hand to connect the other vertebrae so that no movement is allowed during bone fusion (osteosynthesis connection). In current fixing and ~~stabilisation~~stabilization fixings, the dynamic connecting elements are connected to the rigid connecting elements by means of supplementary fixing elements such as dominoes. The use of supplementary pieces has the drawback of increasing the time for mounting the connecting elements on the anchoring elements.

[0034] The ~~present invention~~disclosed structures therefore relate~~[[s]]~~ also to a connecting element for a spinal fixing system, intended to connect at least two implantable connection assemblies, ~~characterised in that it comprises~~ comprising a flexible part extended at one of its ends at least by a rigid part, the ~~said~~ flexible part comprising a cable at least partly surrounded by a polymer envelope, the ~~said~~ cable ~~consisting of~~including at least one elastic strand coaxial with the ~~said~~ envelope.

[0035] The connecting element thus configured makes it possible to offer dynamic and rigid “connections” for vertebrae without having recourse to supplementary fixing elements.

[0036] ~~This~~The connecting element is defined in the remainder of the description as being a “semi-dynamic” connecting element.

[0037] Moreover, and the same as previously, in order not to burden the remainder of the description, the ~~said~~ elastic strand is referred to as the “central strand”.

[0038] Preferably, the ~~said~~ rigid part has a cavity indented to at least partly receive the ~~said~~ cable, the ~~said~~ cavity being blind or through.

[0039] Advantageously, the ~~said~~ cavity is configured ~~so as to~~ cooperate closely with the ~~said~~ cable.

[0040] Advantageously, the ~~said~~ cavity has a zone widened in the direction of the end receiving the ~~said~~ cable.

[0041] Advantageously, the flexible part is fixed to the ~~said~~ rigid part by adhesive bonding, crimping or welding.

[0042] Preferably, the ~~said~~ cable comprises, ~~preferably~~, at least one layer of 6 strands, the ~~said~~ strands being distributed around the ~~said~~ central strand. According to one advantageous configuration ~~of the invention~~, the ~~said~~ cable comprises two layers of successive strands disposed around the ~~said~~ central strand, the first layer of strands surrounding the ~~said~~ central strand consisting of 6 strands, the second layer of strands surrounding the ~~said~~ first layer consisting of 12 strands.

[0043] Advantageously, the strands constituting the layer or layers ~~consist of~~ may be strands twisted around the ~~said~~ central strand.

[0044] Advantageously, the strands of the layer or layers ~~consist~~ may be of a material different from that of the ~~said~~ central strand.

[0045] Advantageously, the central strand has a diameter different from that of the strands of the ~~said~~ layer or layers.

[0046] Advantageously, the strands constituting the layer or layers ~~consist~~ may be of titanium or stainless steel.

[0047] Advantageously, the central strand is tubular.

[0048] Advantageously, the central strand ~~consists~~ may be made of a nickel-titanium alloy, titanium, stainless steel or polymer, such as for example PEEK or polyurethane.

[0049] Advantageously, the ~~said~~ envelope is made from polyurethane or PEEK or ~~consists of~~ a biocompatible fabric.

[0050] ~~The present invention~~Our structures also relate[[s]] to a spinal fixing system comprising at least two implantable connection assemblies connected by means of at least one or two previously described connecting elements.

~~[0051] The invention will be understood better with the help of the description given below, purely by way of explanation, of an embodiment of the invention, with reference to the accompanying figures:~~

~~—— figure 1 illustrates a lateral view in perspective of a dynamic connecting element according to the invention;~~

~~—— figure 2 illustrates a variant embodiment of the connecting element of figure 1;~~

~~—— figure 3 illustrates a view in section of the connecting element of figure 2;~~

~~—— figure 4 illustrates a partial view in perspective of a spinal fixing system comprising rigid connecting elements and dynamic connecting elements according to the invention; and~~

~~—— figure 5 illustrates a view in section of a semi-dynamic connecting element according to a preferred embodiment of the invention.~~

[0052] ~~The~~Turning now to the Drawings, the connecting elements (1) depicted in ~~figures~~Figs. 1 to 4 constitute dynamic connections as defined above. These connecting elements are intended to connect at least two implantable connection assemblies.

[0053] The connecting element (1) illustrated in ~~figure~~Fig. 1 consists of a cable (2) surrounded by a relatively flexible envelope (3). The ~~said~~ cable (2) for its part consists of an elastic strand or stem.

[0054] Strand means a strand consisting either of a single piece (“monostrand”) or of several fibres.

[0055] Advantageously, the ~~said~~-strand is coaxial with the ~~said~~-envelope (3) ~~so as to~~ constitute the central core of the ~~said~~-connecting element (1).

[0056] Hereinafter, the ~~said~~-cable (2) will be referred to as the “central strand”, and will also be referenced under the number (2).

[0057] The ~~said~~-envelope (3) consists of a flexible polymer, such as polyurethane or PEEK (polyetheretherketone). In a particular configuration ~~of the invention~~, the ~~said~~-sheath is a bio-compatible fabric.

[0058] In parallel, in order to offer the necessary return ~~in order to~~ oppose the pivoting movements of the vertebrae around these discs, the ~~said~~-cable, when it comprises only a single strand, advantageously consists of a titanium alloy, PEEK, or a superelastic alloy of the nickel/titanium alloy type, also known by the name Nitinol®.

[0059] ~~In order to improve the characteristic relating to the elasticity of the connecting element,~~ One or more layers of successive strands are disposed around the ~~said~~-central strand (2) to improve the characteristic relating to the elasticity of the connecting element.

[0060] ~~Figures~~Figs. 2 and 3 illustrate in particular a connecting element (1) comprising a layer (4) of 6 strands (40) distributed around the ~~said~~-central strand (2).

[0061] Advantageously, the ~~said~~-strands (40) are disposed twisted around the ~~said~~-central strand (2).

[0062] According to another ~~preferential embodiment of the invention~~aspect, the ~~said~~-connecting element (1) is ~~characterised~~characterized in that it comprises a second layer of strands, advantageously consisting of 12 strands, and surrounding the said first layer (4) of 6 strands (40).

[0063] These two configurations of layers are here given by way of example. ~~It is of course obvious to a person~~ Those skilled in the art know that the ~~organisation~~organization and number of layers of strands, and the number of strands per layer and their configuration, will depend on the rigidity (or elasticity) required for the ~~said~~-connecting element (1).

[0064] However, the choice of the form and constitution of the cable ~~will be~~is guided by the constraint of the diameter, the purpose being to produce a connecting element with a small diameter (preferably less than or equal to 6 mm) so that the connecting element is as little invasive as possible.

[0065] Just like the central strand (2), the strand of each of the layers are made from elastic materials. Advantageously, the strands constituting the third layers and the central strand (2) are formed from titanium, stainless steel or PEEK.

[0066] It should be noted, however, that it is ~~however~~-not necessary for the strands constituting the ~~said~~-layers to be produced from the same material as that from which the ~~said~~-central strand (2) is produced.

[0067] Likewise, the ~~said~~-central strand (2) can also have a form or dimensions different from that of the strands constituting the ~~said~~-layers. In particular, ~~according to a particular configuration of the invention,~~ the ~~said~~-central strand (2) ~~consists~~may be in the shape of a tube. In this case, the ~~said~~-central strand is preferably made from PEEK, the strands of the ~~said~~-layers being made from titanium or stainless steel.

[0068] ~~Figure~~Fig. 4 illustrates a partial view in perspective of a spinal fixing system (100).

[0069] The ~~said~~-fixing system comprises a plurality of implantable connection assemblies. Only three of these implantable connection assemblies are shown in ~~figure~~Fig. 4, these three connection assemblies being respectively referenced 110, 120, 130.

[0070] Each connection assembly is respectively connected to an adjoining connection assembly by a connecting element. In particular, in this example ~~embodiment~~, the connection assembly (110) is connected to the connection assembly (120) by means of a spinal osteosynthesis connecting element, the connection assembly (120) being connected to the connection assembly (130) by means of a dynamic connecting element according to one of the ~~embodiments~~ structures illustrated in ~~figures~~ Figs. 1 to 3.

[0071] The combination of dynamic connecting elements and spinal osteosynthesis connecting elements thus makes it possible to offer a modular fixing system comprising conventional connecting elements of the osteosynthesis connection type and dynamic connecting elements.

[0072] ~~Figure~~ Fig. 5 illustrates a view in section of a connecting element (10) ~~according to a preferred embodiment of the invention~~. The ~~said~~ connecting element (10) is advantageous in that it constitutes a “semi-dynamic” connection.

[0073] The ~~said~~ connecting element (10), in the form of a rod, consists of a flexible part (11) and a rigid part (12), the ~~said~~ rigid part (12) being fixed in line with the ~~said~~ flexible part (11). The “semi-dynamic” ~~behaviour~~ behavior of the ~~said~~ connecting element (10) is conferred by each of the parts (11, 12), the flexible part (11) fulfilling the role of dynamic connection and the rigid part (12) the role of osteosynthesis connection.

[0074] Advantageously, the ~~said~~ flexible part (11) consists of a cable (13) at least partly surrounded by a polymer envelope (14), the ~~said~~ cable (13) consisting of at least one elastic strand coaxial with the ~~said~~ envelope (14). The ~~said~~ cable (13) has at one of its ends a bared zone (17) of the ~~said~~ envelope (14).

[0075] The rigid part (12) has a blind cavity (15) in which the bared zone (17) of the ~~said~~ cable (13) ~~comes to be~~is housed. Advantageously, the ~~said~~ cavity (15) is configured ~~so as to~~ permit close cooperation with the ~~said~~-cable (13).

[0076] Through its constitution and its function, the ~~said~~-flexible part (11), and therefore the ~~said~~-cable, is regularly subjected to oscillations. However, such a movement generates a risk of shearing of the ~~said~~-cable (13).

[0077] This is because the ~~said~~-cable (13) is bent against the cutting edges formed by the lateral walls of the ~~said~~-cavity (15) and the face constituting the end of the rigid part (12). Thus, and ~~in order to~~ limit this risk of shearing, the ~~said~~-cavity (15) has, on the emerging end, a widened zone (16).

[0078] The principle for producing the ~~said~~-connecting element (10) is as follows.

[0079] The ~~said~~-blind cavity (15) is formed longitudinally in the rigid part (12) by piercing. The cable (13) is then introduced into the ~~said~~-cavity (15) until it reaches the closed end of the ~~said~~-cavity (15). The part of the cable (13) inserted in the cavity (15) is fixed therein by adhesive bonding or crimping. Once the cable (13) is disposed and fixed in the cavity (15) in the rigid part (12), the final step consists of forming the envelope (14) by injecting a polymer around the part of the cable (13) not inserted in the cavity (15).

[0080] Advantageously, the ~~said~~-connecting element (10) is produced so that the ~~said~~-cable (13) is coaxial with the rigid part (12).

[0081] As in the examples described above, the ~~said~~-cable (13) consists either of a single elastic strand or an elastic strand surrounded by one or more successive layers of strands, the ~~said~~ strands of the ~~said~~-layers advantageously being twisted.

[0082] Moreover, the description given above relating to the constitution and configuration of the central strand and of the strands in the layers also applies in the context of this configuration.

[0083] Moreover, it is naturally evident that the semi-dynamic connecting element (10) is not limited to the configuration illustrated in ~~figure~~Fig. 5. This is because it is naturally evident that the flexible part can advantageously be extended on each side by a rigid part.

[0084] Likewise, in the case of a multilevel vertebrae fixing and ~~stabilisation~~stabilization system, the strand of the flexible part and ~~[[of]]~~the rigid part or parts ~~will depends~~ on the type of connection required between each adjacent vertebra.

[0085] Finally, the dynamic connecting element can advantageously be formed by a plurality of flexible parts separated from one another by a rigid part.

[0086] The ~~invention is~~structures described above ~~by way of~~are non-limiting examples. ~~Naturally a person~~One skilled in the art is in a position to implement different variants of the ~~invention without for all that~~ departing from the scope of the ~~patent~~appended claims.